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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,146	03/31/2005	Martin A Smith	58142(45858)	2874

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EXAMINER	
TUNG, JOYCE	
ART UNIT	PAPER NUMBER
1637	
MAIL DATE	DELIVERY MODE
08/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,146	SMITH ET AL.	
	Examiner	Art Unit	
	Joyce Tung	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17,18,20-34 and 66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,17,18,20-34 and 66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed 5/15/09 to the Office action has been entered. Claims 1-15, 17-18, 20-35 and 66 are pending.

1. Applicant's arguments with respect to claims 1-15, 17-18, 20-35 and 66 have been considered but are moot in view of the new ground(s) of rejection.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-15, 17-18, 20-35 and 66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrases "subsequently contacting intact cells", "subsequently drying" and "a single solution" as amended in the response filed 5/30/09 have no support in the specification. Thus it constitutes new matter.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-11, 14-15, 17, 20, 26, 28-30, 32-35 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 6,645,717, issued Nov. 11, 2003)

Smith et al. disclose a medium for storage of a genetic material and a method for storing the genetic material. The medium includes a support for immobilizing a genetic material and a coating associated with the support for enabling cellular lysis and releasing the genetic material from the lysed cells (see column 4, lines 10-17). The method includes the steps of immobilizing the genetic material on the support and while enabling cellular lysis and releasing the genetic material from the lysed cells. The genetic material is eluted (see column 4, lines 18-25). The blood is spotted to the filter membrane of the invention, air dried for two minutes and stored at room temperature for 19 weeks (see column 17, lines 66-67 and column 18, lines 1-6). The medium is a plurality of fibers with disordered structure (see column 5, lines 45-46 and fig. 9). The filter media is cellulose-based (see column 6, lines 35-37). The chemical coating solution includes a week base, chelating agent, an anionic surfactant or detergent which can be sodium dodecyl sulfate and urate salt (see column 6, lines 62-67 and column 7, lines 1-2). The nucleic

acid-containing material is whole blood cell containing genomic DNA (see column 13, lines 16-17). Nucleic acids obtained from lysed cultured bacterial cells and mammalian cells are immobilized (see column 7, lines 32-43). The support is heated between 65^0C and 100^0C for elution (see column 8, lines 51-58). In one of the examples the filter membrane is washed several times before elution (see column 15, lines 47-59).

Regarding claims 3 and 6-9, Smith et al. disclose that the blood is spotted to the filter membrane of the invention, air dried for two minutes and stored at room temperature for 19 weeks (see column 17, lines 66-67 and column 18, lines 1-6).

Regarding claim 5, Smith et al. disclose that in one of the examples the filter membrane is washed several times before elution (see column 15, lines 47-59).

Regarding claim 4, Smith et al. disclose that the genetic material is eluted from the medium (see column 4, lines 18-25).

Regarding claims 10-11, Smith et al. disclose that the medium is a plurality of fibers with disordered structure (see column 5, lines 45-46 and fig. 9).

Regarding claims 14-15, Smith et al. disclose that the filter media is cellulose-based (see column 6, lines 35-37).

Regarding claims 17, and 20, Smith et al. disclose that the chemical coating solution includes a week base, chelating agent, an anionic surfactant or detergent which can be sodium dodecyl sulfate and urate salt (see column 6, lines 62-67 and column 7, lines 1-2).

Regarding claim 26, Smith et al. do not explicitly disclose that a chaotrope is used in his invention. However, in the method of Smith et al. as disclosed, there is no a chaotrope used and suggested.

Regarding claims 28-29, Smith et al. disclose that the support is heated between 65^0C and 100^0C for elution (see column 8, lines 51-58).

Regarding claims 30, and 32-34, Smith et al. disclose that the nucleic acid-containing material is whole blood cell containing genomic DNA (see column 13, lines 16-17). Nucleic acids obtained from lysed cultured bacterial cells and mammalian cells are immobilized (see column 7, lines 32-43).

Regarding step c of claim 1, and claim 2, step c of claim 35 and step c of claim 66, Smith et al. do not explicitly disclose removing contaminants when the cells are retained with a solid medium or before drying step f.

Smith et al. discuss the advantage of using microporous filter membranes in which the desired molecule is captured and unwanted components in a fluid phase is removed at higher throughput (see column 2, lines 6-13).

One of ordinary skill in the art would have been motivated to apply the step of removing contaminants when the cells are retained with a solid medium and prior to drying step f because of the advantage of using microporous filter membranes in a fluid phase to remove unwanted components at higher throughput (see column 2, lines 6-13). It would have been prima facie obvious to remove contaminants when cells are retained with a solid medium and prior to drying step f.

6. Claims 12, 21-25, 27, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (6645717, issued Nov. 11, 2003) as applied to claims 1-11, 14-15, 17, 20, 26, 28-30, 32-35 and 66 above, and further in view of Mitchell et al. (WO 00/21973, issued April 20, 2000).

The teachings of Smith et al. are set forth in section 5 above. Smith et al. do not disclose the limitations of claims 12, 21-25, 27 and 31.

Regarding claim 12, Mitchell et al. disclose a method of isolating nucleic acid in which the filter used in the method comprises a plurality of fibers and the fiber diameters are selected from the range of 1um to 10 um (See pg. 9, third paragraph).

Regarding claims 21 and 27, Mitchell et al. disclose that the retentate comprises condensed nuclear material (see pg. 3, third paragraph).

Regarding claim 22, Mitchell et al. disclose that there is a solution for rupturing intact whole cells to leave condensed nuclear material and a lysis solution for lysing nuclear material (See pg. 3, third paragraph).

Regarding claims 23-24, Mitchell et al. disclose that the nucleic aid is retained by the filter substantially in the absence of ionic interaction (See pg. 2, last paragraph),

Regarding claim 25, Mitchell et al. disclose that the nucleic aid is retained by physically regarding the movement of nucleic acid down the filter (see pg. 3, first paragraph).

Regarding claim 31, Mitchell et al. disclose that white cells containing the nucleic acid are retained by the filter as a retentate (see pg. 6, third paragraph and pg. 32, claim 24).

One of ordinary skill in the art would have been motivated to apply a fiber diameters selected from the range of 1um to 10um and the techniques of Mitchell et al. for condensing material from a cellular nucleus, rupturing intact whole cells retained by a solid phase medium to leave condensed material on the medium, lysing the condensed material, retaining nucleic acid on the medium by non-ionic interaction and physical retarding movement of nucleic acid through a solid phase medium because these techniques were well known in the art and by doing so the

method substantially improves the yield and purity of nucleic acid products (see pg. 6, last paragraph). It would have been prima facie obvious to apply these techniques as claimed for isolating and storing nucleic acid.

7. Claims 13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (6645717, issued Nov. 11, 2003) as applied to claims 1-11, 14-15, 17, 20, 26, 28-30, 32-35 and 66 above, and further in view of Mullis (5,187,083, issued Feb, 16, 1993).

The teachings of Smith et al. are set forth in section 5 above. Smith et al. do not disclose the size of the filter pore as recited in claim 13 and the concentration of SDS as recited in claim 18.

Regarding claim 13, Mullis discloses a method for obtaining substantially purified DNA from a biological sample (See column 3, lines 21-22). The filter includes a surface that reversibly and specifically retains DNA. The pore size is from about 0.2 microns to about 0.8 microns. A preferred filter comprises a membrane filter comprised of cellulose acetate and nitrocellulose having a pore size of 0.45 microns (See column 3, lines 44-54, column 7, line 44-45, column 10, lines 16-29, column 15, lines 25).

Regarding claim 18, Mullis discloses that the concentration of SDS used in cell lysis buffer is 1% (see column 9, lines 20 and column 10, line 19).

One of ordinary skill in the art would have been motivated to apply the filter of Mullis with the pore size which is from about 0.2 microns to about 0.8 microns and the lysis buffer containing 1% of SDS because the filter and the lysis buffer of Mullis are used in obtaining substantially purified DNA from a biological sample (See column 3, lines 21-22). It would have

been prima facie obvious to apply the filter of Mullis with the pore size which is from about 0.2 microns to about 0.8 microns and the lysis buffer containing 1% of SDS for isolating nucleic acid as claimed.

Summary

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Joyce Tung/
Examiner, Art Unit 1637

August 20, 2009

/Teresa E Strzelecka/

Primary Examiner, Art Unit 1637

August 23, 2009